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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/421,635      | 10/19/1999  | MARK A. REILEY       | 1759.16690          | 4414             |

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EXAMINER

MAYNARD, JENNIFER J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3763

DATE MAILED: 07/10/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/421,635

Applicant(s)

REILEY

Examiner

Jennifer J Maynard

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 103***

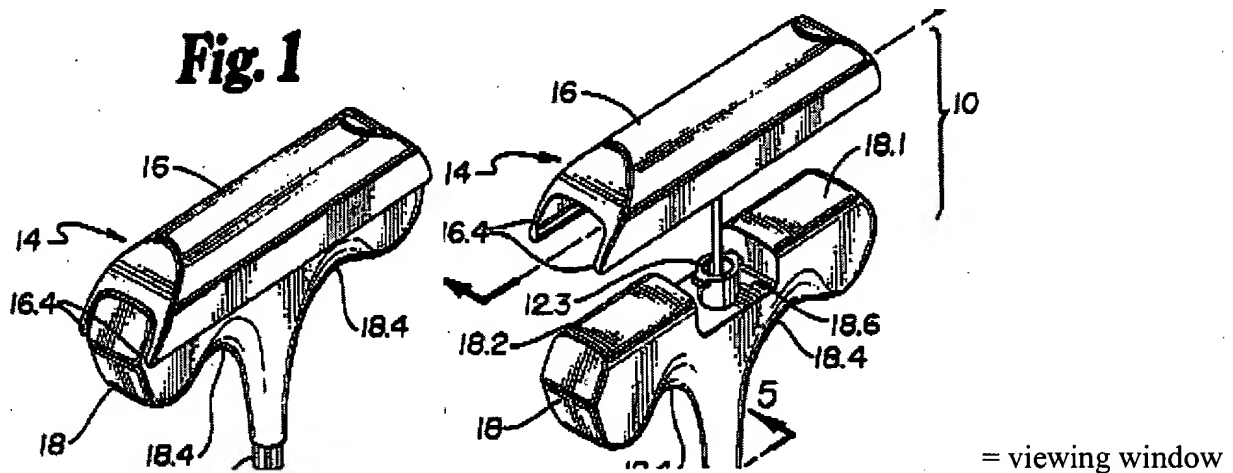
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13, 18-23, 25, 33-38 and 41 are rejected under 35 U.S.C. 103(a) as obvious over Strasser et al. (US 4,838,282 A) in view of Yen Kong Woo (US 3,943,932 A).

Strasser et al. disclose a tool comprising a first instrument (14) having a first handle (16), with a viewing window (no reference numeral, interpreted as being the portion of the handle which is an upside down u-shaped window which receives a tapered, u-shaped shoulder of the second handle in a complementary manner, see Figures 1 and 2) and a second instrument (12) having a second handle (18); both instrument handles are disclosed as being made of an ABS thermoplastic molding material (e.g. "Cyclocac") see Column 5, lines 24-27. \*\*The Examiner references Applicant's specification with regard to identifying material compositions, which are heat-sensitive, deformable materials, i.e. Lustran. It was well known in the art that Lustran was categorized as an ABS (Acrylonitrile-Butadiene-Styrene) thermoplastic. Strasser et al.'s thermoplastic molding material is also an ABS, however the trade name given is that of Cyclocac. It is inherent that the ABS materials have identical or extremely similar physical traits thus Applicant's claim language is anticipated by Strasser et al.'s device.

However if Applicant disagrees with the Examiner's position that the physical traits are inherent, the Examiner has taken the position that in the alternative, it would have been a matter of obvious design choice to one having ordinary skill in the art at the time the invention was made to have manufactured Strasser et al.'s handles out of Lustran, as both Cycolac and Lustran are ABS thermoplastic materials and would be interchangeable as they both have the same physical properties.

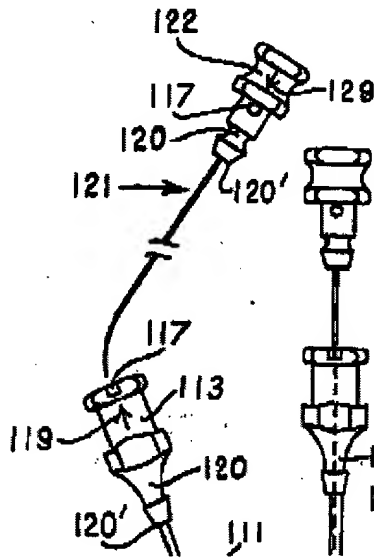


<sup>10</sup> =surfaces intended to be modified with markers, as taught by Woo (US 3,943,932 A)

Strasser et al. fails to disclose a marker on a surface of the second handle which is essentially flush with the surface and fits into the viewing window.

Woo (US 3,943,932 A) discloses an acupuncture device comprising a first instrument (21, 121) with a first marker (129) on a handle portion (22, 122) and a second marker (19, 119) on a handle portion (13, 113) of a second instrument (11, 111).

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It would have been obvious to one having ordinary skill in the art to have utilized a die-cut type marker on the handle portions of Strasser et al., as taught by Woo, so as to provide an alternative mechanism for providing visual indication of the alignment of the tips of the instruments relative to one another during insertion, as Strasser et al. stresses the importance of proper bevel alignment. Additionally, it would have been obvious to one having ordinary skill in the art to have placed the respective markers on one side of the two handle portions' surfaces, as the structural engagement of the two handle portions inherently creates a flush composite handle, and further this location of the markers would ensure that the alignment of the markers would be visible by a user looking down on the composite handle as this would provide the most easily viewed site for the point of reference most often relied upon by the user.

Claims 14-17, 22, 29, 32, 39 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strasser et al. (US 4,838,282 A) in view of Woo (US 3,943,932 A), as applied to Claims 11-13, 18-23, 25, 33-38 and 41 above, and further in view of Webster (4,820,755 A).

Strasser et al. in view of Woo disclose the invention as claimed with the exception of at least one of the handles of the tool comprising a material that indicates whether at least one of the handles has been sterilized by at least one radiation and sterilization chemicals.

Webster discloses polymers, such as polyolefins, and especially polypropylene for use in making medical instruments having a radiochromic hindered phenolic stabilizer which results in a blue color change when subjected to a sterilizing dose of gamma irradiation.

It would have been obvious to one having ordinary skill in the art to have made the handle of Strasser et al. in view of Woo's tool out of a polymer, such as polypropylene, which included a radiochromic hindered phenolic stabilizer, so as to ensure proper sterilization following use thus allowing for subsequent use without cross-contamination.

Claims 24, 26-28, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strasser et al. (US 4,838,282 A) in view of Woo (US 3,943,932 A), as applied to Claims 11-13, 18-23, 25, 33-38 and 41 above, and further in view of Bhiwandker et al. (US 3,523,011 A).

Strasser et al. in view of Woo disclose the invention as claimed with the exception of at least one of the handles of the tool comprising a material that indicates whether at least one of the handles has been sterilized by using heat.

Bhiwandker et al. disclose a sterilization indicator material and tape containing the same for application to medical or surgical instruments. The indicator reacts with steam utilized during the sterilization process.

It would have been obvious to one having ordinary skill in the art to have applied Bhiwandker et al.'s indicator to the handle of Strasser et al. in view of Woo's tool, so as to

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provide means for indicating that proper sterilization heat had been applied to the instrument thus allowing for subsequent use without cross-contamination.

Claims 27, 30, 31, 32, 39, 40, 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strasser et al. (US 4,838,282 A) in view of Woo (US 3,943,932 A), as applied to Claims 11-13, 18-23, 25, 33-38 and 41 above, and further in view of Olson (US 3,258,312 A).

Strasser et al. in view of Woo disclose the invention as claimed with the exception of at least one of the handles of the tool comprising a material that indicates whether at least one of the handles has been sterilized by using a gas.

Olson discloses a sterilization indicator material for monitoring adequate diffusion of ethylene oxide for application to medical or surgical instruments. The indicator reacts with ethylene oxide utilized during the sterilization process, resulting in a color change.

It would have been obvious to one having ordinary skill in the art to have applied Olson's indicator to the handle of Strasser et al. in view of Woo's tool, so as to provide means for indicating that proper diffusion of ethylene oxide had occurred during sterilization of the instrument thus allowing for subsequent use without cross-contamination.

### ***Response to Arguments***

Applicant's arguments filed 09 June 2003 have been considered but are moot in view of the new grounds of rejection.

### ***Conclusion***


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703.872.9302 for regular communications and 703.872.9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

J Maynard  
June 30, 2003



BRIAN L. CASLER  
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